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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) 05-470		
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]	Application Number 10/538,150		Filed June 8, 2005	
on	First Named Inventor			
Signature	Sharon Katrina Watson et al.			
olgitature	Art Unit	T	Examiner	
Typed or printed name	2624		John W. Lee	
Applicant requests review of the final rejection in the above-with this request.	identified app	plication. No a	mendments are being filed	
This request is being filed with a notice of appeal.				
The review is requested for the reason(s) stated on the attac Note: No more than five (5) pages may be provided		).		
I am the				
applicant/inventor.	/A. Bla	/A. Blair Hughes/		
	-		Signature	
assignee of record of the entire interest.  See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.	A. Bla	ir Hughes		
(Form PTO/SB/96)	Typed or printed name		or printed name	
attorney or agent of record.				
Registration number 32,901	312.9	13 2123	phone number	
attorney or agent acting under 37 CFR 1.34.	September 10, 2008			
Registration number if acting under 37 CFR 1.34	_		Date	
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.				
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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE (Case No. 05-470)

In the Applic	cation of:	)	
Shar	on Katrina Watson et al	) Examiner: Jol	nn W. Lee
Serial No.	10538150	) ) Group Art Uni	. 2624
Filed:	June 8, 2005	) Conf. No. 149	
Title:	Image Analysis	) Com. No. 145	"
Commission	ner for Patents		

Sir:

### PRE-APPEAL BRIEF REQUEST FOR REVIEW REMARKS

Pre-appeal brief review is requested for the above application. This paper sets forth Applicant's concise statement of clear errors in the Examiner's final rejection.

#### I. BACKGROUND

Alexandria, VA 22313-1450

Claims 1-18, 20, 22 and 25 are pending in the application. Claims 1, 6-9, 11, 14, 17-18, 20, 22 and 25 stand finally rejected for being anticipated by the Madachy article. Claims 2-5, 10 and 12-13 stand finally rejected for being obvious over the Madachy in view of the Netsch article.

The application includes independent claims 1 and 22 each of which are reproduced immediately below.

- 1. A method for the automated analysis of a digital image comprising an array of pixels, including the successive steps of:
- (a) identifying the locations of objects within the image which have specified intensity and size characteristics;
- (b) defining respective regions of specified extent within the image around respective said locations;
- (c) deriving from the data within respective said regions one or more respective closed contours comprising points of equal intensities; and

- (d) estimating the curvature of at least one respective said contour within respective said regions and producing at least a measure of any concavity thereof.
- 22. A method for the automated identification of mitotic activity from a digital image of a histological specimen, including the successive steps of:
- (a) identifying the locations of objects within the image which have specified intensity and size characteristics associated with epithelial cell nuclei;
- (b) defining respective regions of specified extent within the image around respective said locations;
- (c) deriving from the data within respective said regions one or more respective closed contours comprising points of equal intensities;
- (d) estimating the curvature of at least one respective said contour within respective said regions and producing at least a measure of any concavity thereof: and
- (e) classifying objects as representing mitotic cell nuclei as a function of at least said measure of concavity of a contour corresponding to the respective object.

# II. THE EXAMINER FAILED TO REBUT APPLICANT'S PATENTABILITY POSITIONS

MPEP §706.07 requires the examiner to provide a statement of grounds for rejection. The statement of grounds can include a reiteration of the grounds for rejection raised in prior office actions. However, the statement "should include a rebuttal of any arguments raised in the applicant's reply."

The examiner's final rejection did not include a rebuttal of the patentability positions raised by the applicant in their November 6, 2007 Office Action reply. This has made it difficult for the applicant to respond to the examiner's final rejection because – despite a telephonic conversation with the examiner about his rebuttal of the applicant's arguments – the applicant still does not know exactly why the examiner rejected their patentability positions. For this reason, the examiner is asked to withdraw the final rejection and issue a new non-final rejection including a rebuttal of amplicant's arguments in favor of claim patentability.

#### III. TRAVERSE OF THE ANTICIPATION REJECTION

The examiner rejected claims 1, 6-9, 11, 14, 17-18, 20, 22 and 25 for being anticipated by the Madachy article. The rejected claims are novel and patentable for at least each of the three separate reasons discussed below.

### A. Madachy Does Not Disclose Claim 1 And 22 Steps (a) And (b)

Claims 1, 6-9, 11, 14, 17-18, 20, 22 and 25 are novel and patentable because Madachy does not disclose either step of (a) identifying "locations" of objects; or (b) defining "regions" as claimed in independent claims 1 and 22. The first step (a) of independent claims 1 and 22 — which is not disclosed by Madachy - is to identify the locations of objects within an image which have specified intensity and size characteristics. (See the section headed "Location of candidate cell nuclei" on pages 5-9 of the present application). The second step (b) of independent claims 1 and 22 - which is also not disclosed by Madachy - is to define respective regions of specified extent within the image around respective said locations (these are the regions of interest (ROI)), from the data within which regions closed contours are subsequently derived. (See specification section titled "Contour selection" on pages 10-14).

The Examiner alleges that the reference to "geometrical measures" in the Abstract of Madachy corresponds to the claimed first step of claims 1 and 22. That is not the case however, because there is no disclosure whatsoever in the Madachy Abstract about identifying the *locations* of objects as required by step (a) of claims 1 and 22.

The Examiner next alleges that the SHAPE section of the Madachy reference discloses the "defining" step (b) of claims 1 and 22. Once again, however, there is no disclosure whatsoever in the cited Madachy section regarding the step (b) feature of defining regions of specified extent within the image around specified locations. What actually occurs in Madachy is described in the METHOD section of the Article. According to the METHOD section, the Madachy analysis program uses a pre-specified density threshold and contours are then sought in the thresholded image. For each of these reasons, claims 1, 6-9, 11, 14, 17-18, 20, 22 and 25 are novel and patentable.

# B. Madachy Does Not Disclose Claim Steps (a) and (b) Performed in Succession

Claims 1, 6-9, 11, 14, 17-18, 20, 22 and 25 are novel and patentable because Madachy also does not disclose successive steps of (a) identifying; and (b) defining as claimed in independent claims 1 and 22. There is absolutely no disclosure in Madachy of the independent claim 1 and 22 successive steps of *first* identifying the *locations* of objects having specified intensity and size characteristics and then defining *respective* (i.e. individual) regions around the *respective* locations within which to seek contours.

The examiner took the position during applicant's teleconference with him that it did not matter in what order the steps occur because the claim term "including the successive steps of . . . " is found in the claim preamble and, therefore, can be ignored. The examiner reached this conclusion without any apparent evaluation of the patent application as a whole. A review of the claims and application as a whole shows the "successive step" limitation in the preamble is meaningful and moreover it causes the claims to be novel over Madachy.

A claim preamble is limiting (i.e. it must be given patentable weight) if it recites essential structure or steps, or if it is necessary to give life, meaning and validity to the claim. Pitney Bowes Inc. v. Hewlett-Packard Company, 182 F.3d. 1298-1305 (Fed. Cir. 1999). The determination of whether a preamble recitation is a structural limitation is resolved only by reviewing the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim. Bell Communications v. Vitalink Communications, 55 F.3d. 615, 621 (Fed. Cir. 1995). A proper analysis of the specification and claims in this case demonstrates that the preamble term "successive steps of" should be given patentable weight because the specification consistently describes the methods being performed successively as claimed. As a result, claims 1, 6-9, 11, 14, 17-18, 20, 22 and 25 are novel and patentable.

## C. Madachy Does Not Disclose A "Measure Of Concavity"

Claims 1, 6-9, 11, 14, 17-18, 20, 22 and 25 are also novel and patentable because Madachy does not disclose a method that produces a measure of concavity of the curvature of derived contours as required by independent claims 1 and 22. (See page 19, lines 12-23 of the present application). It is the examiner's position that the curvature R(i) at points around the contour as mentioned in the SHAPE section of Madachy discloses this claim feature.

Individual values of curvature around the contour as described in Madachy are not themselves a measure of concavity of the contour, however. While Madachy indicates that a set of curvatures is used to derive so-called "bending energy" there is no express disclosure of using curvature data to produce a measure of *concavity* of the contour.

Even though the measurement of curvature R(i) at points around the contour of Madachy could result in a measurement of concavity, if the curvature data was suitably processed to do so, Madachy does not disclose or suggest that this is or should be done. The measurement of curvature alone does not result in a measurement of concavity and the most important point is that Madachy does not teach that you should use that data to measure concavity. So Madachy does not expressly disclose a measure of concavity.

Moreover, producing a measure of concavity is not inherent from Madachy. In order for a prior art reference to have an inherent feature or step, a structure or step in the prior art must necessarily function in accordance with the anticipated claim feature. In re King, 231 USPQ 136, 138 (Fed. Cir. 1986). That is clearly not the case because there are many measures that can be made from the measurement of curvature R(i) of Madachy. Hence, a measure of concavity is not an inherent feature of Madachy because the measure of curvature which he discloses would not be used in all instances to produce a measure of concavity. Moreover, the Federal Circuit has confirmed that inherency may not be established by probabilities or possibilities. The mere fact that a thing may result from a given set of circumstances is not sufficient to establish inherency. Continental Can Co. v. Monsanto Co., 948 F.2d. 1264, 1269, 20 USPQ 2<sup>nd</sup> 1746, 1749 (Fed. Cir. 1991). Therefore, claims 1, 6-9, 11, 14 17-18, 20 and 22 are novel at least because Madachy does not disclose a step that produces a measure of concavity.

#### IV. THE OBVIOUSNESS REJECTION

The examiner rejected claims 2-5, 10 and 12-13 for being obvious over the Madachy article in view of the Netsch article. Claims 2-5, 10 and 12-13 are non-obvious and patentable by virtue of their dependence upon independent claim 1, which is patentable at least for the reasons recited in section III above.

Date: September 9, 2008 By: <u>/A. Blair Hughes/</u>
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